JUN 2 1 2001

K011616

7.0 510(k) Summary

510(k) Summary
(As required by 21 C.F.R. § 807.92)

Submitted By:	Inverness Medical Technology, Inc. 51 Sawyer Road Suite 200 Waltham, MA 02453-3448 Phone: (781) 647-3900 Fax: (781) 647-3939
Contact Person:	Carol A. Adiletto, M.S. Director of Clinical and Regulatory Affairs Phone: (781) 314-4002 Fax: (781) 647-3939 e-mail: carol.adiletto@usa.invernessmedical.com
Date Summary Prepared:	May 24, 2001
Device Name:	InDuo™ Blood Glucose Meter
Classification Name:	The InDuo™ Blood Glucose Meter is a Class II Device for home use, as per 21 CFR § 862.1345.
Substantial Equivalence:	The InDuo™ Blood Glucose Meter is substantially equivalent to the previously cleared predicate device (K002134).
Description of Changes:	The changes made to the meter were done under design controls, and include ergonomic changes to allow for inclusion of the InDuo™ Insulin Doser to form a single unit for user convenience.
Statement of Intended Use:	The InDuo™ Blood Glucose Meter is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. The InDuo™ meter is intended for use outside the body (*in vitro* diagnostic use) by healthcare professionals and by diabetics at home as an aid to monitor the effectiveness of diabetes control. The InDuo™ Blood Glucose Meter also functions as the cap for the InDuo™ Insulin Doser. The two devices fit together to form a single unit for user convenience.
Technological Characteristics:	The modified device has the same technological characteristics as the legally marketed predicate.
Summary of Performance Data:	Laboratory and clinical studies demonstrate that the InDuo™ Blood Glucose Meter provides equivalent performance to the ONE TOUCH® Ultra™ Blood Glucose Meter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 1 2001

Ms. Carol A. Adiletto, M.S.
Director of Clinical and Regulatory Affairs
Inverness Medical Technology, Inc.
51 Sawyer Road – Suite 200
Waltham, MA 02453

Re: 510(k) Number: K011616
Trade/Device Name: LifeScan InDuo™ Blood Glucose Meter
Regulation Number: 862.1345, 880.5860
Regulatory Class: II
Product Code: NBW, CGA, FMF
Dated: May 24, 2001
Received: May 25, 2001

Dear Ms. Adiletto:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

3.0 ODE Indications for Use Statement

Indications for Use Statement

510(k) Number: K011616

Device Name: LifeScan InDuo™ Blood Glucose Meter

Indications for Use:

The InDuo™ Blood Glucose Meter is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. The InDuo™ Blood Glucose Meter is intended for use outside the body (*in vitro* diagnostic use) by healthcare professionals and by diabetics at home as an aid to monitor the effectiveness of diabetes control.

The InDuo™ Blood Glucose Meter also functions as the cap for the InDuo™ Insulin Doser. The two devices fit together to form a single unit for user convenience.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
10(k) Number K011616

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR Over-the-Counter Use ✓
(Per 21 CFR 801.109)